REMARKS/ARGUMENTS

Applicants have amended claims 1 and 17 to recite "in an amount of from 5 μg per cm^2 to 10,000 μg per cm^2" and have canceled claim 14. Applicants have amended claim 16 to correct a typographical error. Applicants have also amended claims 2 and 6 and have added claim 26. These amendments are supported by the specification including the original claims. Applicants respectfully request entry of these amendments. Claims 1-13 and 15-26 are currently pending.

Claims 2 and 6 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. With respect to the rejection of claim 2 for insufficient antecedent basis, current claim 2 recites "wherein the active ingredient as applied to the matrix is in a solvent" and provides sufficient antecedent basis for the remainder of claim 2. With respect to the rejection of claim 6 for reciting a narrow range or limitation that falls within a broad range or limitation, Applicants note that "pharmaceutically active ingredients" and "cosmetic skin care additives" are no longer recited in claim 6. Applicants respectfully request withdrawal of these rejections.

Claims 1, 2, 5-8, and 16 stand rejected under 35 U.S.C. §102(b) as anticipated by EP 212 681 (EP '681). Claims 9-12 also stand rejected under 35 U.S.C. §103(a) as being obvious in view of EP '681.

EP '681 does not disclose or suggest a self-adhesive matrix patch comprising an active ingredient applied in an amount of from 5 μg/cm^2 to 10,000 μg/cm^2 in dissolved or liquid form to the first side of the matrix, as claimed in current claims 1, 2, 5-12, and 16. EP '681 indicates "[b]efore the reaction product [forming the polyurethane medical patch] is cured, however, a therapeutically effective amount of the chosen drug or drugs is incorporated into the composition.... The cured polyurethane is a solid and contains the selected drug dispersed throughout the polyurethane." Column 4, lines 46-49 and column 5, lines 38-40. Because the drug is provided throughout the polyurethane forming the medical patch, EP '681 does not

disclose or suggest a self-adhesive medical patch with an active ingredient applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ to the first side of the matrix. There is also no motivation or suggestion for modifying EP '681 so that the active ingredient is applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ to the first side of the matrix. Applicants thus respectfully request withdrawal of the rejections based on this reference.

Claims 1, 2, 5-8, 11, 12 and 16 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,839,174 (US '174). US '174 discloses a nicotine-loaded matrix "prepared by dissolving a polyether-type polyurethane in an appropriate solvent, adding liquid nicotine and homogenizing the mixture" which is then cast onto a backing material. Column 3, lines 19-24. As with the medical patch of EP '681 above, US '174 does not disclose or suggest a self-adhesive medical patch comprising an active ingredient applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form to the first side of the matrix, as claimed in current claims 1, 2, 5-8, 11, 12, and 16 but rather the nicotine is provided in the polyurethane matrix. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 1, 3, 6-10, 16-20, 23 and 24 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,958,447 (US '447). US '447 is directed to transdermal matrix patches manufactured from prefabricated, commercially-available pressure-sensitive adhesive tapes. However, US '447 does not disclose or suggest a matrix with an active ingredient applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form to the first side of the matrix; wherein the matrix remains adhesive on the first side even after application of the active ingredient. US '447 is silent as to the amount of active ingredient which may be applied in dissolved or liquid form, and most of the embodiments in US '447 are directed to application of an active ingredient in powder form. For those embodiments in US '447 where a bioactive liquid or semiliquid substance is applied, described therein as "Inter-Laminar Matrix Diffusion (ILMD)," the liquid is applied to the patch with either an embossed liner with liquid contained in depressions/pits or by half-tone printing a pattern of dots, preferably over 25% of the surface. See columns 10-11, particularly column 10, lines 24-29 and column 10, line 65 - column 11, line 7. US '447 does not disclose or suggest the amount of active ingredient of 5 $\mu g/cm^2$ to 10,000

$\mu g/cm^2$ in dissolved or liquid form applied to the matrix as set forth in the present claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 3, 4 and 17-25 stand rejected under 35 U.S.C. §103(a) as obvious in view of the combination of EP '681 and U.S. Patent No. 4,915,950 (US '950). Claims 3, 4, 9, 10 and 17-25 stand rejected under 35 U.S.C. §103(a) obvious in view of the combination of US '174 and US '950. As indicated above, EP '681 discloses incorporating a drug into reactant products that react to form a polyurethane and US '174 discloses dissolving a polyurethane in a solvent, adding nicotine, and homogenizing the mixture. In both EP '681 and US '174, the mixture is then cast to form a patch comprising the drug. US '950 discloses depositing a drug in liquid form on a source layer, preferably made from a non-woven fabric, and laminating a contact adhesive layer onto the source layer, wherein the face of the contact adhesive layer opposite that of the source layer may contact the skin. See columns 5-6, Figure 2. Thus, US '950 does not disclose or suggest applying the matrix with the active ingredient to the side of the matrix intended for skin or wound contact wherein the matrix remains adhesive on that side even after application of the active ingredient. Furthermore, US '950 does not disclose or suggest applying the active ingredient in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form as recited in the claims. Because none of US '174, EP '681 or US '950 discloses or suggests an absorbent, self-adhesive matrix with an active ingredient applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form to the side of the matrix intended for skin or wound contact wherein the matrix remains adhesive on that side even after application of the active ingredient, the combination of these references also does not disclose or suggest this subject matter of the claims. Accordingly, Applicants respectfully request withdrawal of these rejections.

Claims 2, 4 and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US '447 in view of US '950. As explained above, US '447 does not disclose or suggest the amount of active ingredient of 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form applied to the matrix, and US '950 does not cure the deficiency of the teachings in US '447. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 11-15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over EP '681 in view of U.S. Patent No. 6,419,935 (US '935). Claims 13-15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US '174 in view of US '935. Claims 13-15 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over US '447 in view of US '935. As explained above, none of EP '681, US '174, nor US '447 disclose or suggest an active ingredient applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form to the first side of the matrix. US '935 discloses a cosmetic skin treatment patch comprising a self adhesive matrix with a variable thickness, preferably 5 microns to 500 microns and optionally including D- or DL-panthenol. US '935 does not disclose the amount of active ingredient which may be applied to a patch in dissolved or liquid form or where it may be applied. Thus, US '935 also does not disclose or suggest an active ingredient applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form to a matrix, or even applied to the first side of the matrix. Accordingly, the combination of EP '681, US '174, or US '447 and US '935 does not disclose or suggest a self-adhesive medical patch comprising an active ingredient applied in an amount of from 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form to the first side of the matrix. Therefore, Applicants respectfully request withdrawal of these rejections.

Claims 5, 11, 12, 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. '447 in view of U.S. Patent No. 5,844,013 (US '013). As explained above, US '447 does not disclose or suggest the amount of active ingredient of 5 $\mu g/cm^2$ to 10,000 $\mu g/cm^2$ in dissolved or liquid form applied to the matrix. US '013 discloses hydrophobic polyurethane gel foams with self-adhesive properties that may be used as wound dressings. However, US '013 does not cure the deficiencies of the teachings of US '447. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 1 and 5-12 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of claims 1-7, 12, 19-22, 26-28, 33, 37, and 38 of copending application No. 10/735,310. An Office Action for U.S. Application No. 10/735,310 was mailed February 14, 2006, and no response has been submitted to date by applicants to that

Office Action. Accordingly, Applicants request that the examiner hold this rejection in abeyance in the event that the '310 application is not further pursued.

Applicants respectfully submit that all the claims are in condition for allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor informalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. (571) 273-8300 on the date shown below.

Cynthia V. Hall — July 17, 2006

Cynthia V. Hall — Date